510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	November 27. 2013
Submitter:	GE Healthcare (GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC) 3030 Ohmeda Drive P.O. Box 7550 Madison, WI 53707
Primary Contact Person:	Chris Paulik Regulatory Affairs Leader GE Healthcare (GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC) Telephone: (262) 548-2010 Email: Christopher.Paulik@med.ge.com
Secondary Contact Person:	Steven Kachelmeyer Regulatory Affairs Director GE Healthcare (GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC) Telephone: (262) 548 2432 Email: Steven.Kachelmeyer@med.ge.com
Device Trade Name:	Lunar DPX Series: (DPX-MD+, DPX-MD+ Compact , DPX-NT, DPX-NT Compact, DPX Pro, DPX Bravo, DPX Duo) Lunar Prodigy Series: (Prodigy, Prodigy Compact, Prodigy Pro, Prodigy Pro Compact, Prodigy Primo, Prodigy Primo Compact, Prodigy Advance, Prodigy Advance Compact, Prodigy Forma) Lunar iDXA Series: (iDXA, iDXA Advance, iDXA Pro, iDXA Forma, Lunar iDXA)
Common/Usual Name:	Bone Densitometer
Classification Names: Product Code:	Bone Densitometer (21CFR 892.1170) KGI

Predicate Device(s):	Pediatric Reference Data for Prodigy and DPX Bone Densitometers (K001812) Infant Whole Body Software Option for QDR Densitometers (K042480) Expert-XL Orthopedic Hip Acquisition and Analysis Software (K972517)
Device Description:	enCORE software is used on GE Lunar DXA bone densitometers. Release 16 of the enCORE software (enCORE 16 or enCORE 16.xx) includes some feature enhancements. The software will now expand upon its previously cleared pediatric indication (K001812) by providing a "Complete Pediatric" software that can measure the bone mineral content (BMC), bone mineral density (BMD) and body composition (lean body mass and fat mass) in patients from birth to 20 years of age. The software will also provide a comparison of measured variables obtained by dual energy x-ray absorptiometry to a database of reference values for patients 5-19 years of age. The software will also expand its previously cleared orthopedic hip indication (K972517) to include estimates of the BMD of the knee before and after joint implant. The GE Lunar DXA bone densitometers measure the bone mineral density (BMD), lean and fat tissue mass and calculate derivative values of bone mineral content (BMC), area, soft tissue mass, regional soft tissue mass, total soft tissue mass, fat free mass, regional/total soft tissue mass ratio, % fat, region % fat, total body % fat, Android % fat, Gynoid % fat, Android/Gynoid ratio (A/G ratio) and Body Mass Index (BMI).
Intended Use:	The enCORE version 16 for GE Lunar DXA Bone Densitometers is intended for medical purposes to measure bone density, bone mineral content, and fat and lean tissue content by x-ray transmission measurements through the bone and adjacent tissues.
Technology:	The enCORE version 16 Software Release for the GE Lunar DXA Bone Densitometers employs the same fundamental scientific technology as its predicate device, which is dual-energy x-ray absorptiometry using a PC based image processing algorithm running on a Microsoft Windows operating system. The enCORE version 16 Software Release for the GE Lunar DXA Bone Densitometers has expanded the anatomical sites from the predicate devices to now also include the knee for orthopedic examinations, pre and post joint implant, with its optional orthopedic software. The enCORE version 16 Software Release for the GE Lunar DXA Bone Densitometers has expanded the patient population from the predicate devices for the complete pediatric software option to accommodate those populations from birth to 20 years of age.

	The differences discussed in this section do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The enCORE version 16 Software Release for the GE Lunar DXA Bone Densitometers and its applications comply with voluntary standards. The following quality assurance measures were applied to the development of the system: ▪ Risk Analysis ▪ Requirements Reviews ▪ Design Reviews ▪ Testing on unit level (Module verification) ▪ Integration testing (System verification) ▪ Performance testing (Verification) ▪ Safety testing (Verification) ▪ Simulated use testing (Validation) Summary of Clinical Tests: The subject of this premarket submission, enCORE version 16 Software Release for the GE Lunar DXA Bone Densitometers, did not require clinical studies to support substantial equivalence. Bench testing was performed to verify the effectiveness of the expanded population range of the "Complete Pediatric" software application from birth to 20 years as well as add the knee as an additional anatomic site for the orthopedic software application.
Conclusion:	The enCORE version 16 Software Release for the GE Lunar DXA Bone Densitometers expands upon its previously cleared pediatric indication (K001812) by broadening the patient population from birth to 20 years of age. The software will also expand its previously cleared orthopedic hip indication (K972517) to include estimates of the BMD of the knee before and after joint implant. It does not result in any new potential safety risks, has the same technological characteristics, and performs as well as the devices currently on the market. After analyzing performance testing on the bench it is the conclusion of GE Healthcare that the enCORE version 16 Software Release for the GE Lunar DXA Bone Densitometers e is substantially equivalent to other marketed devices with similar indications for use and meeting the same standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 15, 2014

GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC
% Mr. Chris Paulik
Regulatory Affairs Leader
3030 Ohmeda Drive
MADISON WI 53718

Re: K133664
Trade/Device Name: enCORE version 16 software for GE Lunar DXA Bone Densitometers
Regulation Number: 21 CFR 892.1170
Regulation Name: Bone densitometer
Regulatory Class: II
Product Code: KGI
Dated: April 9, 2014
Received: April 10, 2014

Dear Mr. Paulik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133664

Device Name
enCORE version 16 for GE Lunar DXA Bone Densitometers

Indications for Use *(Describe)*
The optional "Complete Pediatric" software option measures bone mineral content (BMC), bone mineral density (BMD) and body composition (lean body mass and fat mass) in patients from birth to 20 years of age. The software provides a comparison of measured variables obtained by dual energy x-ray absorptiometry to a database of reference values for patients 5-19 years of age. These data can be used for comparative purposes at the sole discretion of the physician. The software does not provide a reference population for comparative purposes for patients younger than 5 years of age.

Optional Orthopedic software estimates periprosthetic BMD of an orthopedic hip or knee implant (pre- and post-surgery).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*